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AND G.D. SEARLE LLC

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN FRANCISCO DIVISION

IN RE BEXTRA AND CELEBREX  
MARKETING, SALES PRACTICES AND  
PRODUCTS LIABILITY LITIGATION

*This document relates to*  
DANIEL FARRIER,

Plaintiff,

vs.

PFIZER, INC., PHARMACIA CORPORATION,  
and G.D. SEARLE LLC, (FKA G.D. SEARLE &  
CO.),

Defendants.

) MDL Docket No. 1699  
)  
) CASE NO. 3:07-cv-4817-CRB  
)  
) **PFIZER INC., PHARMACIA**  
) **CORPORATION, AND G.D.**  
) **SEARLE LLC'S ANSWER TO**  
) **COMPLAINT**  
)  
) **JURY DEMAND ENDORSED**  
) **HEREIN**

1 NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiff's Complaint as  
 2 "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation ("Pharmacia"), and G.D. Searle LLC  
 3 ("Searle"), (collectively "Defendants") and file their Answer to Plaintiff's Complaint  
 4 ("Complaint"), and would respectfully show the Court as follows:

5 **I.**

6 **PRELIMINARY STATEMENT**

7 The Complaint does not state in sufficient detail when Plaintiff was prescribed or used  
 8 Celebrex® (celecoxib) ("Celebrex®"). Accordingly, this Answer can only be drafted  
 9 generally. Defendants may seek leave to amend this Answer when discovery reveals the  
 10 specific time periods in which Plaintiff was prescribed and used Celebrex®.

11 **II.**

12 **ANSWER**

13 **Response to Allegations Regarding Parties**

14 1. Defendants admit that Plaintiff brought this civil action seeking monetary damages, but  
 15 deny that Plaintiff is entitled to any relief or damages. Defendants admit that, during certain  
 16 periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United  
 17 States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
 18 accordance with their approval by the FDA. Defendants admit that, during certain periods of  
 19 time, Celebrex® were manufactured and packaged for Searle, which developed, tested,  
 20 marketed, co-promoted, and distributed Celebrex® in the United States to be prescribed by  
 21 healthcare providers who are by law authorized to prescribe drugs in accordance with their  
 22 approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used  
 23 in accordance with its FDA-approved prescribing information. Defendants state that the  
 24 potential effects of Celebrex® were and are adequately described in its FDA-approved  
 25 prescribing information, which was at all times adequate and comported with applicable  
 26 standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused  
 27 Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the  
 28 Complaint.

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2. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

3. Defendants admit that Pfizer is a Delaware corporation with its principal place of business in New York. Defendants admit that, as the result of a merger in April 2003, Pharmacia became a subsidiary of Pfizer. Defendants state that the allegations in this paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States, including Oklahoma, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

4. Defendants admit that Searle is a Delaware limited liability company with its principal place of business in Illinois. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

5. Defendants admit that Pharmacia is a Delaware corporation with its principal place of business in New Jersey. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain periods of time, Pharmacia marketed and co-promoted Celebrex® in the United States, including Oklahoma, to be prescribed by healthcare providers

1 who are by law authorized to prescribe drugs in accordance with their approval by the FDA.  
2 Defendants deny the remaining allegations in this paragraph of the Complaint.

3 6. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a  
4 merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit  
5 that, during certain periods of time, Pharmacia marketed and co-promoted Celebrex® in the  
6 United States to be prescribed by healthcare providers who are by law authorized to prescribe  
7 drugs in accordance with their approval by the FDA. Defendants deny the remaining  
8 allegations in this paragraph of the Complaint.

9 **Response to Allegations Regarding Jurisdiction and Venue**

10 7. Defendants are without knowledge or information to form a belief as to the truth of the  
11 allegations in this paragraph of the Complaint regarding the amount in controversy, and,  
12 therefore, deny that the same. However, Defendants admit that Plaintiff claims that the amount  
13 in controversy exceeds \$75,000, exclusive of interests and costs.

14 8. Defendants are without knowledge or information to form a belief as to the truth of the  
15 allegations in this paragraph of the Complaint regarding Plaintiff's citizenship and the amount  
16 in controversy, and, therefore, deny the same. However, Defendants admit that Plaintiff claims  
17 that the parties are diverse and the amount in controversy exceeds \$75,000, exclusive of  
18 interests and costs.

19 9. Defendants are without knowledge or information to form a belief as to the allegations  
20 in this paragraph of the Complaint regarding the judicial district in which the asserted claims  
21 allegedly arose and, therefore, deny the same. Defendants state that Celebrex® was and is safe  
22 and effective when used in accordance with its FDA-approved prescribing information.  
23 Defendants deny committing a tort in the States of California and Oklahoma, and deny the  
24 remaining allegations in this paragraph of the Complaint.

25 10. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
26 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who  
27 are by law authorized to prescribe drugs in accordance with their approval by the FDA.  
28 Defendants admit that, during certain periods of time, Celebrex® was manufactured and

1 packaged for Searle, which developed, tested, marketed, co-promoted and distributed  
2 Celebrex® in the United States to be prescribed by healthcare providers who are by law  
3 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit  
4 that Pfizer, Pharmacia, and Searle are registered to and do business in the State of California.  
5 Defendants state that the allegations in this paragraph of the Complaint regarding “predecessors  
6 in interest” are vague and ambiguous. Defendants are without knowledge or information  
7 sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same.  
8 Defendants deny committing a tort in the States of California and Oklahoma, and deny the  
9 remaining allegations in this paragraph of the Complaint.

10 **Response to Allegations Regarding Interdistrict Assignment**

11 11. Defendants state that this paragraph of the Complaint contains legal contentions to  
12 which no response is required. To the extent that a response is deemed required, Defendants  
13 admit that this case should be transferred to In re: Bextra and Celebrex Marketing, Sales Prac.  
14 and Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial  
15 Panel on Multidistrict Litigation on September 6, 2005.

16 **Response to Factual Allegations**

17 12. Defendants are without knowledge or information sufficient to form a belief as to the  
18 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
19 Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this  
20 paragraph of the Complaint.

21 13. Defendants are without knowledge or information sufficient to form a belief as to the  
22 truth of the allegations in this paragraph of the Complaint regarding Plaintiff’s medical  
23 condition and whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants  
24 state that Celebrex® was and is safe and effective when used in accordance with its FDA-  
25 approved prescribing information. Defendants state that the potential effects of Celebrex®  
26 were and are adequately described in its FDA-approved prescribing information, which was at  
27 all times adequate and comported with applicable standards of care and law. Defendants deny  
28 the remaining allegations in this paragraph of the Complaint.

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14. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

15. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and consumers without substantial change from the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

16. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

17. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

18. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used

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1 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
2 effective when used in accordance with its FDA-approved prescribing information. Defendants  
3 deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny  
4 the remaining allegations in this paragraph of the Complaint.

5 19. Defendants are without knowledge or information sufficient to form a belief as to the  
6 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
7 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
8 effective when used in accordance with its FDA-approved prescribing information. Defendants  
9 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
10 approved prescribing information, which was at all times adequate and comported with  
11 applicable standards of care and law. Defendants deny any wrongful conduct, deny that  
12 Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this  
13 paragraph of the Complaint.

14 20. Defendants are without knowledge or information sufficient to form a belief as to the  
15 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
16 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
17 effective when used in accordance with its FDA-approved prescribing information. Defendants  
18 deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny  
19 the remaining allegations in this paragraph of the Complaint.

20 21. Defendants are without knowledge or information sufficient to form a belief as to the  
21 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
22 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
23 effective when used in accordance with its FDA-approved prescribing information. Defendants  
24 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
25 approved prescribing information, which was at all times adequate and comported with  
26 applicable standards of care and law.

27 22. Defendants state that Celebrex® was and is safe and effective when used in accordance  
28 with its FDA-approved prescribing information. Defendants state that the potential effects of



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1 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
2 which was at all times adequate and comported with applicable standards of care and law.  
3 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage,  
4 and deny the remaining allegations in this paragraph of the Complaint.

5 23. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or  
6 damage, and deny the remaining allegations in this paragraph of the Complaint.

7 24. Defendants state that the allegations in this paragraph of the Complaint regarding  
8 aspirin, naproxen, and ibuprofen are not directed toward Defendants, and, therefore, no  
9 response is required. Defendants admit that Celebrex® is in a class of drugs that are, at times,  
10 referred to as being non-steroidal anti-inflammatory drugs (“NSAIDs”). Plaintiff does not  
11 allege having used Bextra® in the Complaint. Nevertheless, Defendants state that, as stated in  
12 the FDA-approved labeling for Bextra®, “[t]he mechanism of action is believed to be due to  
13 inhibition of prostaglandin synthesis primarily through inhibition of cyclooxygenase-2 (COX-  
14 2).” Defendants state that allegations in this paragraph of the Complaint regarding Vioxx® are  
15 not directed toward Defendants, and therefore no response is required. To the extent that a  
16 response is deemed required, Plaintiff fails to provide the proper context for the allegations in  
17 this paragraph of the Complaint regarding Vioxx®. Defendants therefore lack sufficient  
18 information or knowledge to form a belief as to the truth of such allegations and, therefore,  
19 deny the same. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff  
20 injury or damage, and deny the remaining allegations in this paragraph of the Complaint.  
21 Defendants deny the remaining allegations in this paragraph of the Complaint.

22 25. Defendants state that the allegations in this paragraph of the Complaint are not directed  
23 towards Defendants and, therefore, no response is required. To the extent that a response is  
24 deemed required, Defendants state that Plaintiff fails to provide the proper context for the  
25 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information  
26 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

27 26. Defendants state that the allegations in this paragraph of the Complaint are not directed  
28 towards Defendants and, therefore, no response is required. To the extent that a response is



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1 deemed required, Defendants state that Plaintiff fails to provide the proper context for the  
2 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information  
3 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

4 27. Defendants state that the allegations in this paragraph of the Complaint are not directed  
5 towards Defendants and, therefore, no response is required. To the extent that a response is  
6 deemed required, Defendants state that Plaintiff fails to provide the proper context for the  
7 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information  
8 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

9 28. Defendants state that the allegations in this paragraph of the Complaint are not directed  
10 towards Defendants and, therefore, no response is required. To the extent that a response is  
11 deemed required, Defendants state that Plaintiff fails to provide the proper context for the  
12 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information  
13 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

14 29. Defendants state that the allegations in this paragraph of the Complaint regarding “other  
15 pharmaceutical companies” are not directed towards Defendants and, therefore, no response is  
16 required. To the extent a response is deemed required, Defendants state that, as stated in the  
17 FDA-approved labeling for Celebrex®, “[t]he mechanism of action of Celebrex is believed to  
18 be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2  
19 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the  
20 cyclooxygenase-1 (COX-1) isoenzyme.” Plaintiff fails to provide the proper context for the  
21 remaining allegations in this paragraph and Defendants therefore lack sufficient information or  
22 knowledge to form a belief as to the truth of the allegations and, therefore, deny the remaining  
23 allegations in this paragraph of the Complaint.

24 30. Defendants state that the allegations in this paragraph of the Complaint regarding  
25 “predecessors in interest” are vague and ambiguous. Defendants are without knowledge or  
26 information sufficient to form a belief as to the truth of such allegations, and, therefore, deny  
27 the same. Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he  
28 mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis,

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1 primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in  
2 humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme.” Defendants  
3 state that Celebrex® was and is safe and effective when used in accordance with its FDA-  
4 approved prescribing information. Defendants state that the potential effects of Celebrex®  
5 were and are adequately described in its FDA-approved prescribing information, which was at  
6 all times adequate and comported with applicable standards of care and law. Defendants deny  
7 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

8 31. Defendants admit that Searle submitted a New Drug Application (“NDA”) for  
9 Celebrex® on June 29, 1998. Defendants admit that, on December 31, 1998, the FDA granted  
10 approval of Celebrex® for the following indications: (1) for relief of the signs and symptoms of  
11 osteoarthritis; and (2) for relief of the signs and symptoms of rheumatoid arthritis in adults.  
12 Defendants admit that, on December 23, 1999, the FDA granted approval of Celebrex® to  
13 reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis  
14 (“FAP”) as an adjunct to usual care (e.g. endoscopic surveillance surgery). Defendants state  
15 that allegations in this paragraph of the Complaint regarding Merck and Vioxx® are not  
16 directed toward Defendants, and therefore no response is required. To the extent that a  
17 response is deemed required, Plaintiff fails to provide the proper context for the allegations in  
18 this paragraph of the Complaint regarding Merck and Vioxx®. Defendants therefore lack  
19 sufficient information or knowledge to form a belief as to the truth of such allegations and,  
20 therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the  
21 Complaint.

22 32. Plaintiff does not allege having used Bextra® in the Complaint. Nevertheless,  
23 Defendants state that, as stated in the FDA-approved labeling for Bextra®, “[t]he mechanism of  
24 action is believed to be due to inhibition of prostaglandin synthesis primarily through inhibition  
25 of cyclooxygenase-2 (COX-2).” Defendants admit, as indicated in the package insert approved  
26 by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of  
27 osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary  
28 dysmenorrhea. Defendants admit that the New Drug Application for Bextra® was filed with

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1 the FDA on January 15, 2001. Defendants state that Plaintiff's allegations in this paragraph of  
2 the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are  
3 without knowledge or information to form a belief as to the truth of such allegations, and,  
4 therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the  
5 Complaint.

6 33. Defendants admit that Celebrex® is in a class of drugs that are, at times, referred to as  
7 being non-steroidal anti-inflammatory drugs ("NSAIDs"). Defendants state that, as stated in  
8 the FDA-approved labeling for Celebrex®, "[t]he mechanism of action of Celebrex is believed  
9 to be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2  
10 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the  
11 cyclooxygenase-1 (COX-1) isoenzyme." Defendants deny the remaining allegations in this  
12 paragraph of the Complaint.

13 34. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
14 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who  
15 are by law authorized to prescribe drugs in accordance with their approval by the FDA.  
16 Defendants admit that, during certain periods of time, Celebrex® was manufactured and  
17 packaged for Searle, which developed, tested, marketed, co-promoted and distributed  
18 Celebrex® in the United States to be prescribed by healthcare providers who are by law  
19 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state  
20 that Celebrex® is a prescription medication which is approved by the FDA for the following  
21 indications: (1) for relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs  
22 and symptoms of rheumatoid arthritis in adults; (3) for the management of acute pain in adults;  
23 (4) for the treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous  
24 colorectal polyps in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g.,  
25 endoscopic surveillance surgery); (6) for relief of signs and symptoms of ankylosing  
26 spondylitis; and (7) for relief of the signs and symptoms of juvenile rheumatoid arthritis in  
27 patients two years of age and older. Defendants deny the remaining allegations in this  
28 paragraph of the Complaint.

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35. Defendants deny the allegations in this paragraph of the Complaint.

36. Defendants state that Celebrex® is a prescription medication which is approved by the FDA for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age and older. Defendants admit that Celebrex® is in a class of drugs that are, at times, referred to as being non-steroidal anti-inflammatory drugs (“NSAIDs”). Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme.” Plaintiff fails to provide the proper context for the remaining allegations in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations and, therefore, deny the same.

37. Defendants state that the allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack knowledge or information sufficient to form a belief as to the truth of such allegations and, therefore, deny the same.

38. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed

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1 Celebrex® in the United States to be prescribed by healthcare providers who are by law  
2 authorized to prescribe drugs in accordance with their approval by the FDA. Plaintiff fails to  
3 provide the proper context for the allegations in this paragraph of the Complaint regarding  
4 “pharmaceutical researchers, scientists, and companies.” Defendants therefore lack knowledge  
5 or information sufficient to form a belief as to the truth of such allegations and, therefore, deny  
6 the same. Defendants deny any wrongful conduct and deny the remaining allegations in this  
7 paragraph of the Complaint.

8 39. Defendants state that the Celebrex® label speaks for itself and respectfully refer the  
9 Court to the Celebrex® label for its actual language and text. Any attempt to characterize the  
10 Celebrex® label is denied. Defendants state that Celebrex® was and is safe and effective when  
11 used in accordance with its FDA-approved prescribing information. Defendants state that the  
12 potential effects of Celebrex® were and are adequately described in its FDA-approved  
13 prescribing information, which was at all times adequate and comported with applicable  
14 standards of care and law. Defendants deny any wrongful conduct and deny the remaining  
15 allegations in this paragraph of the Complaint.

16 40. Defendants are without knowledge or information sufficient to form a belief as to the  
17 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
18 Celebrex® and, therefore, deny the same. Defendants state that the referenced article and  
19 website speaks for themselves and respectfully refer the Court to the article and website for  
20 their actual language and text. Any attempt to characterize the article and website is denied.  
21 Defendants state that Celebrex® was and is safe and effective when used in accordance with its  
22 FDA-approved prescribing information. Defendants deny any wrongful conduct, deny that  
23 Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this  
24 paragraph of the Complaint.

25 41. Defendants state that Celebrex® was and is safe and effective when used in accordance  
26 with its FDA-approved prescribing information. Defendants deny any wrongful conduct and  
27 deny the remaining allegations in this paragraph of the Complaint, including all subparts.  
28

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1 42. Defendants state that Celebrex® was and is safe and effective when used in accordance  
2 with its FDA-approved prescribing information. Defendants state that the potential effects of  
3 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
4 which was at all times adequate and comported with applicable standards of care and law.  
5 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
6 the Complaint, including all subparts.

7 43. Defendants state that the allegations in this paragraph of the Complaint are not directed  
8 towards Defendants and, therefore, no response is required. To the extent that a response is  
9 deemed required, Defendants state that Plaintiff fails to provide the proper context for the  
10 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information  
11 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

12 44. Defendants state that the allegations in this paragraph of the Complaint are not directed  
13 towards Defendants and, therefore, no response is required. To the extent that a response is  
14 deemed required, Defendants state that Plaintiff fails to provide the proper context for the  
15 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information  
16 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

17 45. Defendants state that the allegations in this paragraph of the Complaint are not directed  
18 towards Defendants and, therefore, no response is required. To the extent that a response is  
19 deemed required, Defendants state that Plaintiff fails to provide the proper context for the  
20 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information  
21 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

22 46. Defendants state that the allegations in this paragraph of the Complaint are not directed  
23 towards Defendants and, therefore, no response is required. To the extent that a response is  
24 deemed required, Defendants state that Plaintiff fails to provide the proper context for the  
25 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information  
26 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

27 47. Defendants state that the allegations in this paragraph of the Complaint are not directed  
28 towards Defendants and, therefore, no response is required. To the extent that a response is

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1 deemed required, Defendants state that Plaintiff fails to provide the proper context for the  
2 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information  
3 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

4 48. Defendants state that the allegations in this paragraph of the Complaint are not directed  
5 towards Defendants and, therefore, no response is required. To the extent that a response is  
6 deemed required, Defendants state that Plaintiff fails to provide the proper context for the  
7 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information  
8 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

9 49. Defendants state that the allegations in this paragraph of the Complaint are not directed  
10 towards Defendants and, therefore, no response is required. To the extent that a response is  
11 deemed required, Defendants state that Plaintiff fails to provide the proper context for the  
12 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information  
13 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

14 50. Defendants state that the allegations in this paragraph of the Complaint are not directed  
15 towards Defendants and, therefore, no response is required. To the extent that a response is  
16 deemed required, Defendants state that Plaintiff fails to provide the proper context for the  
17 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information  
18 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

19 51. Defendants state that the allegations in this paragraph of the Complaint are not directed  
20 towards Defendants and, therefore, no response is required. To the extent that a response is  
21 deemed required, Defendants state that Plaintiff fails to provide the proper context for the  
22 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information  
23 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

24 52. Defendants state that the allegations in this paragraph of the Complaint are not directed  
25 towards Defendants and, therefore, no response is required. To the extent that a response is  
26 deemed required, Defendants state that Plaintiff fails to provide the proper context for the  
27 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information  
28 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.



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53. Defendants state that the allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

54. Plaintiff does not allege having used Bextra® in this Complaint. Nevertheless, Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants state that the referenced letter speaks for itself and respectfully refer the Court to the letter for its actual language and text. Any attempt to characterize the letter is denied. Defendants state that the remaining allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the remaining allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

55. Defendants state that the allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

56. Defendants state that the allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

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1 57. Plaintiff does not allege having used Bextra® in this Complaint. Nevertheless,  
2 Defendants state that Bextra® was and is safe and effective when used in accordance with its  
3 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®  
4 were and are adequately described in its FDA-approved prescribing information, which was at  
5 all times adequate and comported with applicable standards of care and law. Defendants state  
6 that the Bextra® label speaks for itself and respectfully refer the Court to the Bextra® label for  
7 its actual language and text. Any attempt to characterize the Bextra® label is denied.  
8 Defendants admit that the sale of Bextra® was voluntarily suspended in the U.S. market as of  
9 April 7, 2005. Defendants deny the remaining allegations regarding Bextra® in this paragraph  
10 of the Complaint. Defendants state that the remaining allegations in this paragraph of the  
11 Complaint are not directed towards Defendants and, therefore, no response is required. To the  
12 extent that a response is deemed required, Defendants state that Plaintiff fails to provide the  
13 proper context for the remaining allegations in this paragraph of the Complaint. Defendants  
14 therefore lack sufficient information or knowledge to form a belief as to the truth of such  
15 allegations and, therefore, deny the same.

16 58. Defendants state that Celebrex® is a prescription medication which is approved by the  
17 FDA for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; (2)  
18 for relief of the signs and symptoms of rheumatoid arthritis in adults; (3) for the management of  
19 acute pain in adults; (4) for the treatment of primary dysmenorrhea; (5) to reduce the number of  
20 adenomatous colorectal polyps in familial adenomatous polyposis (FAP) as an adjunct to usual  
21 care (e.g., endoscopic surveillance surgery); (6) for relief of signs and symptoms of ankylosing  
22 spondylitis; and (7) for relief of the signs and symptoms of juvenile rheumatoid arthritis in  
23 patients two years of age and older. Defendants deny the remaining allegations in this  
24 paragraph of the Complaint.

25 59. Defendants state that the Celebrex® label speaks for itself and respectfully refer the  
26 Court to the Celebrex® label for its actual language and text. Any attempt to characterize the  
27 Celebrex® label is denied. Defendants state that Celebrex® was and is safe and effective when  
28 used in accordance with its FDA-approved prescribing information. Defendants state that the

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1 potential effects of Celebrex® were and are adequately described in its FDA-approved  
2 prescribing information, which was at all times adequate and comported with applicable  
3 standards of care and law. Defendants deny the remaining allegations in this paragraph of the  
4 Complaint.

5 60. Defendants state that the referenced FDA Announcement speaks for itself and  
6 respectfully refer the Court to the FDA Announcement for its actual language and text. Any  
7 attempt to characterize the FDA Announcement is denied. Defendants state that Plaintiff fails  
8 to provide the proper context for the allegations in this paragraph of the Complaint regarding  
9 “all manufacturers of prescription NSAIDs,” and “over-the-counter (OTC) NSAIDs.”  
10 Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of  
11 such allegations and, therefore, deny the same. Defendants deny any wrongful conduct and  
12 deny the remaining allegations in this paragraph of the Complaint.

13 61. Defendants state that the referenced FDA Announcement and Medication Guide speak  
14 for themselves and respectfully refer the Court to the FDA Announcement and Medication  
15 Guide for their actual language and text. Any attempt to characterize the FDA Announcement  
16 is denied. Defendants state that Plaintiff fails to provide the proper context for the allegations  
17 in this paragraph of the Complaint regarding “OTC NSAIDs.” Defendants therefore lack  
18 sufficient information or knowledge to form a belief as to the truth of such allegations and,  
19 therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the  
20 Complaint.

21 62. Defendants state that the allegations in this paragraph of the Complaint are not directed  
22 towards Defendants and, therefore, no response is required. To the extent that a response is  
23 deemed required, Defendants state that Plaintiff fails to provide the proper context for the  
24 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information  
25 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

26 63. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or  
27 damage, and deny the remaining allegations in this paragraph of the Complaint.

28 64. Defendants state that this paragraph of the Complaint contains legal contentions to

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1 which no response is required. To the extent that a response is deemed required, Defendants  
2 deny the allegations in this paragraph of the Complaint.

3 65. Defendants state that this paragraph of the Complaint contains legal contentions to  
4 which no response is required. To the extent that a response is deemed required, Defendants  
5 deny the allegations in this paragraph of the Complaint, including all subparts.

6 66. Defendants state that the potential effects of Celebrex® were and are adequately  
7 described in its FDA-approved prescribing information, which was at all times adequate and  
8 comported with applicable standards of care and law. Defendants deny the remaining  
9 allegations in this paragraph of the Complaint.

10 67. Defendants state that this paragraph of the Complaint contains legal contentions to  
11 which no response is required. To the extent that a response is deemed required, Defendants  
12 state that Celebrex® was and is safe and effective when used in accordance with its FDA-  
13 approved prescribing information. Defendants state that the potential effects of Celebrex®  
14 were and are adequately described in its FDA-approved prescribing information, which was at  
15 all times adequate and comported with applicable standards of care and law. Defendants deny  
16 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

17 68. Defendants state that this paragraph of the Complaint contains legal contentions to  
18 which no response is required. To the extent that a response is deemed required, Defendants  
19 deny the allegations in this paragraph of the Complaint.

20 69. Defendants state that Celebrex® was and is safe and effective when used in accordance  
21 with its FDA-approved prescribing information. Defendants state that the potential effects of  
22 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
23 which was at all times adequate and comported with applicable standards of care and law.  
24 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
25 the Complaint.

26 70. Defendants state that Celebrex® was and is safe and effective when used in accordance  
27 with its FDA-approved prescribing information. Defendants deny any wrongful conduct and  
28 deny the remaining allegations in this paragraph of the Complaint.

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1 71. Defendants state that Celebrex® was and is safe and effective when used in accordance  
2 with its FDA-approved prescribing information. Defendants state that the potential effects of  
3 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
4 which was at all times adequate and comported with applicable standards of care and law.  
5 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
6 the Complaint.

7 72. Defendants are without knowledge or information sufficient to form a belief as to the  
8 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
9 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
10 effective when used in accordance with its FDA-approved prescribing information. Defendants  
11 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
12 approved prescribing information, which was at all times adequate and comported with  
13 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
14 remaining allegations in this paragraph of the Complaint.

15 73. Defendants are without knowledge or information sufficient to form a belief as to the  
16 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
17 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
18 effective when used in accordance with its FDA-approved prescribing information. Defendants  
19 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
20 approved prescribing information, which was at all times adequate and comported with  
21 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
22 remaining allegations in this paragraph of the Complaint.

23 74. Defendants state that the Celebrex® label speaks for itself and respectfully refer the  
24 Court to the article for its actual language and text. Any attempt to characterize the article is  
25 denied. Defendants state that Celebrex® was and is safe and effective when used in accordance  
26 with its FDA-approved prescribing information. Defendants state that the potential effects of  
27 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
28 which was at all times adequate and comported with applicable standards of care and law.

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1 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
2 the Complaint.

3 75. Defendants state that Celebrex® was and is safe and effective when used in accordance  
4 with its FDA-approved prescribing information. Defendants state that the potential effects of  
5 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
6 which was at all times adequate and comported with applicable standards of care and law.  
7 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
8 the Complaint.

9 76. Defendants state that the Celebrex® package insert speaks for itself and respectfully  
10 refer the Court to the package insert for its actual language and text. Any attempt to  
11 characterize the package insert is denied. Defendants state that Celebrex® was and is safe and  
12 effective when used in accordance with its FDA-approved prescribing information. Defendants  
13 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
14 approved prescribing information, which was at all times adequate and comported with  
15 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
16 remaining allegations in this paragraph of the Complaint.

17 77. Defendants state that the Celebrex® package insert speaks for itself and respectfully  
18 refer the Court to the package insert for its actual language and text. Any attempt to  
19 characterize the package insert is denied. Defendants state that Celebrex® was and is safe and  
20 effective when used in accordance with its FDA-approved prescribing information. Defendants  
21 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
22 approved prescribing information, which was at all times adequate and comported with  
23 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
24 remaining allegations in this paragraph of the Complaint.

25 78. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
26 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who  
27 are by law authorized to prescribe drugs in accordance with their approval by the FDA.  
28 Defendants admit that, during certain periods of time, Celebrex® was manufactured and

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1 packaged for Searle, which developed, tested, marketed, co-promoted and distributed  
2 Celebrex® in the United States to be prescribed by healthcare providers who are by law  
3 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state  
4 that Celebrex® was and is safe and effective when used in accordance with its FDA-approved  
5 prescribing information. Defendants state that the potential effects of Celebrex® were and are  
6 adequately described in its FDA-approved prescribing information, which was at all times  
7 adequate and comported with applicable standards of care and law. Defendants deny any  
8 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

9 79. Defendants are without knowledge or information sufficient to form a belief as to the  
10 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
11 Celebrex® and, therefore, deny the same. Defendants admit that, during certain periods of  
12 time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be  
13 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance  
14 with their approval by the FDA. Defendants admit that, during certain periods of time,  
15 Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-  
16 promoted and distributed Celebrex® in the United States to be prescribed by healthcare  
17 providers who are by law authorized to prescribe drugs in accordance with their approval by the  
18 FDA. Defendants state that Celebrex® was and is safe and effective when used in accordance  
19 with its FDA-approved prescribing information. Defendants state that the potential effects of  
20 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
21 which was at all times adequate and comported with applicable standards of care and law.  
22 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
23 the Complaint.

24 80. Defendants state that Celebrex® was and is safe and effective when used in accordance  
25 with its FDA-approved prescribing information. Defendants state that the potential effects of  
26 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
27 which was at all times adequate and comported with applicable standards of care and law.  
28



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1 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
2 the Complaint.

3 81. Defendants state that Celebrex® was and is safe and effective when used in accordance  
4 with its FDA-approved prescribing information. Defendants state that the potential effects of  
5 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
6 which was at all times adequate and comported with applicable standards of care and law.

7 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
8 the Complaint.

9 82. Defendants deny any wrongful conduct and deny the remaining allegations in this  
10 paragraph of the Complaint.

11 83. Defendants state that Celebrex® was and is safe and effective when used in accordance  
12 with its FDA-approved prescribing information. Defendants state that the potential effects of  
13 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
14 which was at all times adequate and comported with applicable standards of care and law.

15 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
16 the Complaint.

17 84. Defendants state that the referenced article speaks for itself and respectfully refer the  
18 Court to the article for its actual language and text. Any attempt to characterize the article is  
19 denied. Defendants state that Celebrex® was and is safe and effective when used in accordance  
20 with its FDA-approved prescribing information. Defendants deny the remaining allegations in  
21 this paragraph of the Complaint.

22 85. Defendants state that the referenced article speaks for itself and respectfully refer the  
23 Court to the article for its actual language and text. Any attempt to characterize the article is  
24 denied. Defendants state that Celebrex® was and is safe and effective when used in accordance  
25 with its FDA-approved prescribing information. Defendants deny the remaining allegations in  
26 this paragraph of the Complaint.

27 86. Defendants state that Celebrex® was and is safe and effective when used in accordance  
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
2 which was at all times adequate and comported with applicable standards of care and law.  
3 Defendants deny the allegations in this paragraph of the Complaint.

4 87. Defendants state that Celebrex® was and is safe and effective when used in accordance  
5 with its FDA-approved prescribing information. Defendants state that the potential effects of  
6 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
7 which was at all times adequate and comported with applicable standards of care and law.  
8 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
9 the Complaint.

10 88. Defendants admit that a supplemental NDA for Celebrex® was submitted to the FDA  
11 on June 12, 2000. Defendants assert that the submission speaks for itself and any attempt to  
12 characterize it is denied. Defendants admit that a Medical Officer Review dated September 20,  
13 2000, was completed by the FDA. Defendants state that the referenced study speaks for itself  
14 and respectfully refer the Court to the study for its actual language and text. Any attempt to  
15 characterize the study is denied. Defendants deny the remaining allegations in this paragraph of  
16 the Complaint.

17 89. Defendants state that the referenced Medical Officer Review speaks for itself and  
18 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any  
19 attempt to characterize the Medical Officer Review is denied. Defendants state that the  
20 referenced Alert for Healthcare Professionals speaks for itself and respectfully refer the Court  
21 to the Alert for Healthcare Professionals for its actual language and text. Any attempt to  
22 characterize the Alert for Healthcare Professionals is denied. Defendants deny the remaining  
23 allegations in this paragraph of the Complaint.

24 90. Defendants state that the referenced study speaks for itself and respectfully refer the  
25 Court to the study for its actual language and text. Any attempt to characterize the study is  
26 denied. Defendants state that the referenced article speaks for itself and respectfully refer the  
27 Court to the article for its actual language and text. Any attempt to characterize the article is  
28 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this

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1 paragraph of the Complaint.

2 91. Defendants state that the referenced Medical Officer Review speaks for itself and  
3 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any  
4 attempt to characterize the Medical Officer Review is denied. Defendants state that the  
5 referenced article speaks for itself and respectfully refer the Court to the article for its actual  
6 language and text. Any attempt to characterize the article is denied. Defendants deny the  
7 remaining allegations in this paragraph of the Complaint.

8 92. Defendants state that the referenced article speaks for itself and respectfully refer the  
9 Court to the article for its actual language and text. Any attempt to characterize the article is  
10 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this  
11 paragraph of the Complaint.

12 93. Defendants state that the referenced articles speak for themselves and respectfully refer  
13 the Court to the articles for their actual language and text. Any attempt to characterize the  
14 articles is denied. Defendants state that the referenced study speaks for itself and respectfully  
15 refer the Court to the study for its actual language and text. Any attempt to characterize the  
16 study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

17 94. Defendants state that the referenced Medical Officer Review speaks for itself and  
18 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any  
19 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining  
20 allegations in this paragraph of the Complaint.

21 95. Plaintiff fails to provide the proper context for the allegations concerning “Public  
22 Citizen” in this paragraph of the Complaint. Defendants therefore lack sufficient information or  
23 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.  
24 Defendants deny the remaining allegations in this paragraph of the Complaint.

25 96. Defendants state that the referenced study speaks for itself and respectfully refer the  
26 Court to the study for its actual language and text. Any attempt to characterize the study is  
27 denied. Plaintiff fails to provide the proper context for the allegations concerning “Public  
28 Citizen” in this paragraph of the Complaint. Defendants therefore lack sufficient information or

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1 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

2 Defendants deny the remaining allegations in this paragraph of the Complaint.

3 97. Defendants admit that there was a clinical trial called APC. Defendants state that the  
4 referenced article speaks for itself and respectfully refer the Court to the article for its actual  
5 language and text. Any attempt to characterize the article is denied. Defendants deny the  
6 remaining allegations in this paragraph of the Complaint.

7 98. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself  
8 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language  
9 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.  
10 Defendants deny the remaining allegations in this paragraph of the Complaint.

11 99. Defendants state that the referenced Medical Officer Review speaks for itself and  
12 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any  
13 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining  
14 allegations in this paragraph of the Complaint.

15 100. Defendants admit that there was a clinical trial called PreSAP. Plaintiff fails to provide  
16 the proper context for the allegations concerning “other Celebrex trials” contained in this  
17 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to  
18 form a belief as to the truth of such allegations and, therefore, deny the same. As for the  
19 allegations in this paragraph of the Complaint regarding the PreSAP study, Defendants state  
20 that the referenced study speaks for itself and respectfully refer the Court to the study for its  
21 actual language and text. Any attempt to characterize the study is denied. Defendants deny the  
22 remaining allegations in this paragraph of the Complaint.

23 101. Defendants state that the referenced article speaks for itself and respectfully refer the  
24 Court to the article for its actual language and text. Any attempt to characterize the article is  
25 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

26 102. Plaintiff fails to provide the proper context for the allegations in this paragraph of the  
27 Complaint regarding Merck and Vioxx®. Defendants therefore lack sufficient information or  
28 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

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1 Defendants state that the referenced studies speak for themselves and respectfully refer the  
2 Court to the studies for their actual language and text. Any attempt to characterize the studies is  
3 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

4 103. Defendants state that the referenced Medical Officer Review speaks for itself and  
5 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any  
6 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining  
7 allegations in this paragraph of the Complaint.

8 104. Defendants state that allegations in this paragraph of the Complaint regarding Vioxx®  
9 are not directed toward Defendants, and therefore no response is required. To the extent that a  
10 response is deemed required, Plaintiff fails to provide the proper context for the allegations in  
11 this paragraph of the Complaint regarding Vioxx® . Defendants therefore lack sufficient  
12 information or knowledge to form a belief as to the truth of such allegations and, therefore,  
13 deny the same. Defendants state that the referenced study speaks for itself and respectfully  
14 refer the Court to the study for its actual language and text. Any attempt to characterize the  
15 study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

16 105. Defendants state that allegations in this paragraph of the Complaint regarding Merck  
17 and Vioxx® in this paragraph of the Complaint are not directed toward Defendants, and  
18 therefore no response is required. To the extent that a response is deemed required, Plaintiff  
19 fails to provide the proper context for the allegations in this paragraph of the Complaint  
20 regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants therefore lack  
21 sufficient information or knowledge to form a belief as to the truth of such allegations and,  
22 therefore, deny the same. Defendants state that the referenced study speaks for itself and  
23 respectfully refer the Court to the study for its actual language and text. Any attempt to  
24 characterize the study is denied. Defendants deny the remaining allegations in this paragraph of  
25 the Complaint.

26 106. Defendants state that allegations in this paragraph of the Complaint regarding Merck  
27 and Vioxx® in this paragraph of the Complaint are not directed toward Defendants, and  
28 therefore no response is required. To the extent that a response is deemed required, Plaintiff

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1 fails to provide the proper context for the allegations in this paragraph of the Complaint  
2 regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants therefore lack  
3 sufficient information or knowledge to form a belief as to the truth of such allegations and,  
4 therefore, deny the same. Defendants state that the referenced study speaks for itself and  
5 respectfully refer the Court to the study for its actual language and text. Any attempt to  
6 characterize the study is denied. Defendants state that the referenced article speaks for itself  
7 and respectfully refer the Court to the article for its actual language and text. Any attempt to  
8 characterize the article is denied. Defendants deny the remaining allegations in this paragraph  
9 of the Complaint.

10 107. Defendants state that Celebrex® was and is safe and effective when used in accordance  
11 with its FDA-approved prescribing information. Defendants deny the allegations in this  
12 paragraph of the Complaint.

13 108. Defendants state that the referenced article speaks for itself and respectfully refer the  
14 Court to the article for its actual language and text. Any attempt to characterize the article is  
15 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

16 109. Defendants state that allegations in this paragraph of the Complaint are not directed  
17 toward Defendants, and therefore no response is required. To the extent that a response is  
18 deemed required, Defendants state that the referenced article speaks for itself and respectfully  
19 refer the Court to the article for its actual language and text. Any attempt to characterize the  
20 article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

21 110. Defendants deny the allegations in this paragraph of the Complaint.

22 111. Defendants state that Celebrex® was and is safe and effective when used in accordance  
23 with its FDA-approved prescribing information. Defendants state that the potential effects of  
24 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
25 which was at all times adequate and comported with applicable standards of care and law.  
26 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the  
27 remaining allegations contained in this paragraph of the Complaint.

28 112. Defendants deny any wrongful conduct and deny the allegations contained in this

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1 paragraph of the Complaint.

2 113. Defendants deny any wrongful conduct and deny the allegations contained in this  
3 paragraph of the Complaint.

4 114. Defendants state that Celebrex® was and is safe and effective when used in accordance  
5 with its FDA-approved prescribing information. Defendants state that the potential effects of  
6 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
7 which was at all times adequate and comported with applicable standards of care and law.  
8 Defendants deny any wrongful conduct and deny the remaining allegations contained in this  
9 paragraph of the Complaint.

10 115. Defendants are without knowledge or information sufficient to form a belief as to the  
11 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
12 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
13 effective when used in accordance with its FDA-approved prescribing information. Defendants  
14 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
15 approved prescribing information, which was at all times adequate and comported with  
16 applicable standards of care and law. Defendants deny any wrongful conduct, deny that  
17 Celebrex® is unreasonably dangerous, and deny the remaining allegations in this paragraph of  
18 the Complaint.

19 116. Defendants admit that the FDA Division of Drug Marketing, Advertising, and  
20 Communications (“DDMAC”) sent a letter to Pfizer dated January 10, 2005. Defendants state  
21 that the referenced letter speaks for itself and respectfully refer the Court to the letter for its  
22 actual language and text. Any attempt to characterize the letter is denied. Defendants admit  
23 that the DDMAC sent a letter to Searle dated October 6, 1999. Defendants state that the  
24 referenced letter speaks for itself and respectfully refer the Court to the letter for its actual  
25 language and text. Any attempt to characterize the letter is denied. Defendants state that the  
26 transcripts of the FDA Arthritis Drugs Advisory Committee hearings speak for themselves and  
27 respectfully refer the Court to the transcripts for their actual language and text. Any attempt to  
28 characterize the transcripts is denied. Defendants state that the referenced study speaks for



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1 itself and respectfully refer the Court to the article for its actual language and text. Any attempt  
2 to characterize the article is denied. Defendants deny the remaining allegations in this  
3 paragraph of the Complaint.

4 117. Defendants state that Celebrex® was and is safe and effective when used in accordance  
5 with its FDA-approved prescribing information. Defendants state that the potential effects of  
6 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
7 which was at all times adequate and comported with applicable standards of care and law.  
8 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-  
9 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by  
10 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
11 admit that, during certain periods of time, Celebrex® was manufactured and packaged for  
12 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the  
13 United States to be prescribed by healthcare providers who are by law authorized to prescribe  
14 drugs in accordance with their approval by the FDA. Defendants deny the remaining  
15 allegations in this paragraph of the Complaint.

16 118. Defendants state that Celebrex® was and is safe and effective when used in accordance  
17 with its FDA-approved prescribing information. Defendants state that the potential effects of  
18 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
19 which was at all times adequate and comported with applicable standards of care and law.  
20 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-  
21 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by  
22 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
23 admit that, during certain periods of time, Celebrex® was manufactured and packaged for  
24 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the  
25 United States to be prescribed by healthcare providers who are by law authorized to prescribe  
26 drugs in accordance with their approval by the FDA. Defendants state that Celebrex® is a  
27 prescription medication which is approved by the FDA for the following indications: (1) for  
28 relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of

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1 rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the  
2 treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps  
3 in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic  
4 surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for  
5 relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age  
6 and older. Defendants deny any wrongful conduct and deny the remaining allegations in this  
7 paragraph of the Complaint.

8 119. Defendants state that Celebrex® was and is safe and effective when used in accordance  
9 with its FDA-approved prescribing information. Defendants state that the potential effects of  
10 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
11 which at all times was adequate and comported with applicable standards of care and law.  
12 Defendants state that Plaintiff's allegations in this paragraph of the Complaint regarding  
13 "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or  
14 information to form a belief as to the truth of such allegations, and, therefore, deny the same.  
15 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the  
16 allegations in this paragraph of the Complaint.

17 120. Defendants state that Celebrex® was and is safe and effective when used in accordance  
18 with its FDA-approved prescribing information. Defendants state that the potential effects of  
19 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
20 which was at all times adequate and comported with applicable standards of care and law.  
21 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-  
22 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by  
23 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
24 admit that, during certain periods of time, Celebrex® was manufactured and packaged for  
25 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the  
26 United States to be prescribed by healthcare providers who are by law authorized to prescribe  
27 drugs in accordance with their approval by the FDA. Defendants deny the remaining  
28 allegations in this paragraph of the Complaint.

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121. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

122. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

123. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

124. Defendants deny the allegations in this paragraph of the Complaint.

125. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.  
2 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
3 the Complaint.

4 126. Defendants state that Celebrex® was and is safe and effective when used in accordance  
5 with its FDA-approved prescribing information. Defendants state that the potential effects of  
6 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
7 which was at all times adequate and comported with applicable standards of care and law.  
8 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
9 the Complaint.

10 127. Defendants are without knowledge or information sufficient to form a belief as to the  
11 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
12 Celebrex® and, therefore, deny the same. Defendants deny any wrongful conduct, deny that  
13 Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this  
14 paragraph of the Complaint.

15 128. Defendants state that Celebrex® was and is safe and effective when used in accordance  
16 with its FDA-approved prescribing information. Defendants state that the potential effects of  
17 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
18 which was at all times adequate and comported with applicable standards of care and law.  
19 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the  
20 remaining allegations in this paragraph of the Complaint.

21 129. Defendants state that Celebrex® was and is safe and effective when used in accordance  
22 with its FDA-approved prescribing information. Defendants state that the potential effects of  
23 Celebrex® are and were adequately described in its FDA-approved prescribing information,  
24 which was at all times adequate and comported with applicable standards of care and law.  
25 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
26 the Complaint.

27 130. Defendants state that Celebrex® was and is safe and effective when used in accordance  
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Celebrex® are and were adequately described in its FDA-approved prescribing information,  
2 which was at all times adequate and comported with applicable standards of care and law.  
3 Defendants state that the referenced study speaks for itself and respectfully refer the Court to  
4 the study for its actual language and text. Any attempt to characterize the study is denied.  
5 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
6 the Complaint.

7 131. Defendants are without knowledge or information sufficient to form a belief as to the  
8 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
9 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
10 effective when used in accordance with its FDA-approved prescribing information. Defendants  
11 state that the potential effects of Celebrex® are and were adequately described in its FDA-  
12 approved prescribing information, which was at all times adequate and comported with  
13 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
14 remaining allegations in this paragraph of the Complaint.

15 **Response to First Cause of Action: Negligence**

16 132. Defendants incorporate by reference their responses to each paragraph of Plaintiff's  
17 Complaint as if fully set forth herein.

18 133. Defendants state that this paragraph of the Complaint contains legal contentions to  
19 which no response is required. To the extent that a response is deemed required, Defendants  
20 admit that they had duties as are imposed by law but deny having breached such duties.  
21 Defendants state that Celebrex® was and is safe and effective when used in accordance with its  
22 FDA-approved prescribing information. Defendants state that the potential effects of  
23 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
24 which was at all times adequate and comported with applicable standards of care and law.  
25 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
26 the Complaint.

27 134. Defendants state that this paragraph of the Complaint contains legal contentions to  
28 which no response is required. To the extent that a response is deemed required, Defendants

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1 admit that they had duties as are imposed by law but deny having breached such duties.  
2 Defendants state that Celebrex® was and is safe and effective when used in accordance with its  
3 FDA-approved prescribing information. Defendants state that the potential effects of  
4 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
5 which was at all times adequate and comported with applicable standards of care and law.  
6 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
7 the Complaint.

8 135. Defendants state that Celebrex® was and is safe and effective when used in accordance  
9 with its FDA-approved prescribing information. Defendants state that the potential effects of  
10 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
11 which was at all times adequate and comported with applicable standards of care and law.  
12 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
13 the Complaint, including all subparts.

14 136. Defendants are without knowledge or information sufficient to form a belief as to the  
15 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
16 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
17 effective when used in accordance with its FDA-approved prescribing information. Defendants  
18 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
19 approved prescribing information, which was at all times adequate and comported with  
20 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
21 remaining allegations in this paragraph of the Complaint.

22 137. Defendants state that Celebrex® was and is safe and effective when used in accordance  
23 with its FDA-approved prescribing information. Defendants state that the potential effects of  
24 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
25 which was at all times adequate and comported with applicable standards of care and law.  
26 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
27 the Complaint.

28 138. Defendants are without knowledge or information sufficient to form a belief as to the

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1 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
2 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
3 effective when used in accordance with its FDA-approved prescribing information. Defendants  
4 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
5 approved prescribing information, which was at all times adequate and comported with  
6 applicable standards of care and law. Defendants deny any wrongful conduct, deny that  
7 Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this  
8 paragraph of the Complaint.

9 139. Defendants are without knowledge or information sufficient to form a belief as to the  
10 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
11 Celebrex®, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that  
12 Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this  
13 paragraph of the Complaint.

14 140. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or  
15 damage, and deny the remaining allegations in this paragraph of the Complaint.

16 141. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or  
17 damage, and deny the remaining allegations in this paragraph of the Complaint.

18 **Response to Second Cause of Action: Strict Liability**

19 142. Defendants incorporate by reference their responses to each paragraph of Plaintiff's  
20 Complaint as if fully set forth herein.

21 143. Defendants are without knowledge or information sufficient to form a belief as to the  
22 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
23 Celebrex®, and, therefore, deny the same. Defendants admit that, during certain periods of  
24 time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be  
25 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance  
26 with their approval by the FDA. Defendants admit that, during certain periods of time,  
27 Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-  
28 promoted and distributed Celebrex® in the United States to be prescribed by healthcare



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1 providers who are by law authorized to prescribe drugs in accordance with their approval by the  
2 FDA. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and  
3 consumers without substantial change from the time of sale. Defendants deny the remaining  
4 allegations in this paragraph of the Complaint.

5 144. Defendants state that Celebrex® was and is safe and effective when used in accordance  
6 with its FDA-approved prescribing information. Defendants state that the potential effects of  
7 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
8 which was at all times adequate and comported with applicable standards of care and law.  
9 Defendants deny the remaining allegations in this paragraph of the Complaint.

10 145. Defendants state that Celebrex® was and is safe and effective when used in accordance  
11 with its FDA-approved prescribing information. Defendants state that the potential effects of  
12 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
13 which was at all times adequate and comported with applicable standards of care and law.  
14 Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the  
15 remaining allegations in this paragraph of the Complaint.

16 146. Defendants state that Celebrex® was and is safe and effective when used in accordance  
17 with its FDA-approved prescribing information. Defendants state that the potential effects of  
18 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
19 which was at all times adequate and comported with applicable standards of care and law.  
20 Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the  
21 remaining allegations in this paragraph of the Complaint, including all subparts.

22 147. Defendants are without knowledge or information sufficient to form a belief as to the  
23 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
24 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
25 effective when used in accordance with its FDA-approved prescribing information. Defendants  
26 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
27 approved prescribing information, which was at all times adequate and comported with  
28 applicable standards of care and law. Defendants deny any wrongful conduct, deny that

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1 Celebrex® is defective, deny that Celebrex® caused Plaintiff injury or damage, and deny the  
2 remaining allegations in this paragraph of the Complaint.

3 148. Defendants state that Celebrex® was and is safe and effective when used in accordance  
4 with its FDA-approved prescribing information. Defendants state that the potential effects of  
5 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
6 which was at all times adequate and comported with applicable standards of care and law.  
7 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the  
8 remaining allegations in this paragraph of the Complaint.

9 149. Defendants are without knowledge or information sufficient to form a belief as to the  
10 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
11 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
12 effective when used in accordance with its FDA-approved prescribing information. Defendants  
13 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
14 approved prescribing information, which was at all times adequate and comported with  
15 applicable standards of care and law. Defendants deny any wrongful conduct, deny that  
16 Celebrex® is defective, deny that Celebrex® caused Plaintiff injury or damage, and deny the  
17 remaining allegations in this paragraph of the Complaint.

18 150. Defendants state that Celebrex® was and is safe and effective when used in accordance  
19 with its FDA-approved prescribing information. Defendants state that the potential effects of  
20 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
21 which was at all times adequate and comported with applicable standards of care and law.  
22 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
23 the Complaint.

24 151. Defendants are without knowledge or information sufficient to form a belief as to the  
25 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
26 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
27 effective when used in accordance with its FDA-approved prescribing information. Defendants  
28 state that the potential effects of Celebrex® were and are adequately described in its FDA-

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1 approved prescribing information, which was at all times adequate and comported with  
2 applicable standards of care and law. Defendants deny any wrongful conduct, deny that  
3 Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this  
4 paragraph of the Complaint.

5 152. Defendants state that Celebrex® was and is safe and effective when used in accordance  
6 with its FDA-approved prescribing information. Defendants state that the potential effects of  
7 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
8 which was at all times adequate and comported with applicable standards of care and law.  
9 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
10 the Complaint.

11 153. Defendants are without knowledge or information sufficient to form a belief as to the  
12 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
13 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
14 effective when used in accordance with its FDA-approved prescribing information. Defendants  
15 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
16 approved prescribing information, which was at all times adequate and comported with  
17 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
18 remaining allegations in this paragraph of the Complaint.

19 154. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or  
20 damage, and deny the remaining allegations in this paragraph of the Complaint.

21 155. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or  
22 damage, and deny the remaining allegations in this paragraph of the Complaint.

23 156. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or  
24 damage, and deny the remaining allegations in this paragraph of the Complaint.

25 **Response to Third Cause of Action: Breach of Express Warranty**

26 157. Defendants incorporate by reference their responses to each paragraph of Plaintiff's  
27 Complaint as if fully set forth herein.

28 158. Defendants are without knowledge or information sufficient to form a belief as to the

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1 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
2 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
3 effective when used in accordance with its FDA-approved prescribing information. Defendants  
4 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
5 approved prescribing information, which was at all times adequate and comported with  
6 applicable standards of care and law. Defendants admit that they provided FDA-approved  
7 prescribing information regarding Celebrex®. Defendants deny the remaining allegations in  
8 this paragraph of the Complaint.

9 159. Defendants are without knowledge or information sufficient to form a belief as to the  
10 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
11 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
12 effective when used in accordance with its FDA-approved prescribing information. Defendants  
13 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
14 approved prescribing information, which was at all times adequate and comported with  
15 applicable standards of care and law. Defendants admit that they provided FDA-approved  
16 prescribing information regarding Celebrex®. Defendants deny any wrongful conduct and  
17 deny the remaining allegations in this paragraph of the Complaint, including all subparts.

18 160. Defendants admit that they provided FDA-approved prescribing information regarding  
19 Celebrex®. Defendants deny any wrongful conduct and deny the remaining allegations in this  
20 paragraph of the Complaint.

21 161. Defendants state that Celebrex® was and is safe and effective when used in accordance  
22 with its FDA-approved prescribing information. Defendants state that the potential effects of  
23 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
24 which was at all times adequate and comported with applicable standards of care and law.  
25 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
26 the Complaint.

27 162. Defendants state that Celebrex® was and is safe and effective when used in accordance  
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
2 which was at all times adequate and comported with applicable standards of care and law.  
3 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
4 the Complaint.

5 163. Defendants are without knowledge or information sufficient to form a belief as to the  
6 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
7 Celebrex®, and, therefore, deny the same. Defendants state that the potential effects of  
8 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
9 which was at all times adequate and comported with applicable standards of care and law.  
10 Defendants admit that they provided FDA-approved prescribing information regarding  
11 Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

12 164. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or  
13 damage, and deny the remaining allegations in this paragraph of the Complaint.

14 165. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or  
15 damage, and deny the remaining allegations in this paragraph of the Complaint.

16 166. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or  
17 damage, and deny the remaining allegations in this paragraph of the Complaint.

18 **Response to Fourth Cause of Action: Breach of Implied Warranty**

19 167. Defendants incorporate by reference their responses to each paragraph of Plaintiff's  
20 Complaint as if fully set forth herein.

21 168. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
22 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who  
23 are by law authorized to prescribe drugs in accordance with their approval by the FDA.  
24 Defendants admit that, during certain periods of time, Celebrex® was manufactured and  
25 packaged for Searle, which developed, tested, marketed, co-promoted and distributed  
26 Celebrex® in the United States to be prescribed by healthcare providers who are by law  
27 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny  
28 the remaining allegations in this paragraph of the Complaint.

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1 169. Defendants state that Celebrex® was and is safe and effective when used in accordance  
2 with its FDA-approved prescribing information. Defendants state that the potential effects of  
3 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
4 which was at all times adequate and comported with applicable standards of care and law.  
5 Defendants admit that they provided FDA-approved prescribing information regarding  
6 Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

7 170. Defendants state that Celebrex® was and is safe and effective when used in accordance  
8 with its FDA-approved prescribing information. Defendants state that the potential effects of  
9 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
10 which was at all times adequate and comported with applicable standards of care and law.  
11 Defendants deny the remaining allegations in this paragraph of the Complaint.

12 171. Defendants state that Celebrex® was and is safe and effective when used in accordance  
13 with its FDA-approved prescribing information. Defendants state that the potential effects of  
14 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
15 which was at all times adequate and comported with applicable standards of care and law.  
16 Defendants deny the remaining allegations in this paragraph of the Complaint.

17 172. Defendants state that Celebrex® was and is safe and effective when used in accordance  
18 with its FDA-approved prescribing information. Defendants state that the potential effects of  
19 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
20 which was at all times adequate and comported with applicable standards of care and law.  
21 Defendants deny the remaining allegations in this paragraph of the Complaint.

22 173. Defendants are without knowledge or information sufficient to form a belief as to the  
23 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
24 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
25 effective when used in accordance with its FDA-approved prescribing information. Defendants  
26 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
27 approved prescribing information, which was at all times adequate and comported with  
28 applicable standards of care and law. Defendants admit that they provided FDA-approved

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1 prescribing information regarding Celebrex®. Defendants deny the remaining allegations in  
2 this paragraph of the Complaint.

3 174. Defendants are without knowledge or information sufficient to form a belief as to the  
4 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
5 Celebrex® and, therefore, deny the same. Defendants state that, in the ordinary case,  
6 Celebrex® was expected to reach users and consumers without substantial change from the  
7 time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

8 175. Defendants are without knowledge or information sufficient to form a belief as to the  
9 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
10 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
11 effective when used in accordance with its FDA-approved prescribing information. Defendants  
12 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
13 approved prescribing information, which was at all times adequate and comported with  
14 applicable standards of care and law. Defendants deny any wrongful conduct, deny that they  
15 breached any warranty, and deny the remaining allegations in this paragraph of the Complaint.

16 176. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or  
17 damage, and deny the remaining allegations in this paragraph of the Complaint.

18 177. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or  
19 damage, and deny the remaining allegations in this paragraph of the Complaint.

20 178. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or  
21 damage, and deny the remaining allegations in this paragraph of the Complaint.

22 **Response to Fifth Cause of Action: Fraudulent Misrepresentation and Concealment**

23 179. Defendants incorporate by reference their responses to each paragraph of Plaintiff's  
24 Complaint as if fully set forth herein.

25 180. Defendants state that this paragraph of the Complaint contains legal contentions to  
26 which no response is required. To the extent that a response is deemed required, Defendants  
27 admit that they had duties as are imposed by law but deny having breached such duties.  
28 Defendants state that Celebrex® was and is safe and effective when used in accordance with its



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1 FDA-approved prescribing information. Defendants state that the potential effects of  
2 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
3 which was at all times adequate and comported with applicable standards of care and law.  
4 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
5 the Complaint.

6 181. Defendants state that Celebrex® was and is safe and effective when used in accordance  
7 with its FDA-approved prescribing information. Defendants state that the potential effects of  
8 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
9 which was at all times adequate and comported with applicable standards of care and law.  
10 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
11 the Complaint, including all subparts.

12 182. Defendants state that Celebrex® was and is safe and effective when used in accordance  
13 with its FDA-approved prescribing information. Defendants state that the potential effects of  
14 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
15 which was at all times adequate and comported with applicable standards of care and law.  
16 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
17 the Complaint.

18 183. Defendants are without knowledge or information sufficient to form a belief as to the  
19 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
20 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
21 effective when used in accordance with its FDA-approved prescribing information. Defendants  
22 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
23 approved prescribing information, which was at all times adequate and comported with  
24 applicable standards of care and law. Defendants deny any wrongful conduct, deny that  
25 Celebrex® is defective or unreasonably dangerous, and deny the remaining allegations in this  
26 paragraph of the Complaint.

27 184. Defendants state that Celebrex® was and is safe and effective when used in accordance  
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
2 which was at all times adequate and comported with applicable standards of care and law.  
3 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
4 the Complaint.

5 185. Defendants are without knowledge or information sufficient to form a belief as to the  
6 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
7 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
8 effective when used in accordance with its FDA-approved prescribing information. Defendants  
9 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
10 approved prescribing information, which was at all times adequate and comported with  
11 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
12 remaining allegations in this paragraph of the Complaint.

13 186. Defendants are without knowledge or information sufficient to form a belief as to the  
14 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
15 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
16 effective when used in accordance with its FDA-approved prescribing information. Defendants  
17 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
18 approved prescribing information, which was at all times adequate and comported with  
19 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
20 remaining allegations in this paragraph of the Complaint.

21 187. Defendants are without knowledge or information sufficient to form a belief as to the  
22 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
23 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
24 effective when used in accordance with its FDA-approved prescribing information. Defendants  
25 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
26 approved prescribing information, which was at all times adequate and comported with  
27 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
28 remaining allegations in this paragraph of the Complaint.

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188. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

189. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

190. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

191. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

192. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

1 193. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or  
2 damage, and deny the remaining allegations in this paragraph of the Complaint.

3 **Response to Sixth Cause of Action: Unjust Enrichment**

4 194. Defendants incorporate by reference their responses to each paragraph of Plaintiff's  
5 Complaint as if fully set forth herein.

6 195. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
7 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who  
8 are by law authorized to prescribe drugs in accordance with their approval by the FDA.  
9 Defendants admit that, during certain periods of time, Celebrex® was manufactured and  
10 packaged for Searle, which developed, tested, marketed, co-promoted and distributed  
11 Celebrex® in the United States to be prescribed by healthcare providers who are by law  
12 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny  
13 the remaining allegations in this paragraph of the Complaint.

14 196. Defendants are without knowledge or information sufficient to form a belief as to the  
15 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
16 Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this  
17 paragraph of the Complaint.

18 197. Defendants are without knowledge or information sufficient to form a belief as to the  
19 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
20 Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this  
21 paragraph of the Complaint.

22 198. Defendants are without knowledge or information sufficient to form a belief as to the  
23 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
24 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
25 effective when used in accordance with its FDA-approved prescribing information. Defendants  
26 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
27 approved prescribing information, which was at all times adequate and comported with  
28 applicable standards of care and law. Defendants deny any wrongful conduct and deny the

1 remaining allegations in this paragraph of the Complaint.

2 199. Defendants are without knowledge or information sufficient to form a belief as to the  
3 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
4 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
5 effective when used in accordance with its FDA-approved prescribing information. Defendants  
6 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
7 approved prescribing information, which was at all times adequate and comported with  
8 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
9 remaining allegations in this paragraph of the Complaint.

10 200. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or  
11 damage, and deny the remaining allegations in this paragraph of the Complaint.

12 **Response to Seventh Cause of Action:**

13 **State Consumer Fraud and Deceptive Trade Practices Acts**

14 201. Defendants incorporate by reference their responses to each paragraph of Plaintiff's  
15 Complaint as if fully set forth herein.

16 202. Defendants are without knowledge or information sufficient to form a belief as to the  
17 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
18 Celebrex® and, therefore, deny the same. Defendants state that this paragraph of the Complaint  
19 contains legal contentions to which no response is required. To the extent that a response is  
20 deemed required, Defendants admit that they had duties as are imposed by law but deny having  
21 breached such duties. Defendants deny the remaining allegations in this paragraph of the  
22 Complaint.

23 203. Defendants are without knowledge or information sufficient to form a belief as to the  
24 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
25 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
26 effective when used in accordance with its FDA-approved prescribing information. Defendants  
27 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
28 approved prescribing information, which was at all times adequate and comported with

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1 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
2 remaining allegations in this paragraph of the Complaint.

3 204. Defendants are without knowledge or information sufficient to form a belief as to the  
4 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
5 Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and  
6 effective when used in accordance with its FDA-approved prescribing information. Defendants  
7 state that the potential effects of Celebrex® were and are adequately described in its FDA-  
8 approved prescribing information, which was at all times adequate and comported with  
9 applicable standards of care and law. Defendants deny any wrongful conduct, deny that  
10 Celebrex® caused Plaintiff injury or damage, and deny the remaining allegations in this  
11 paragraph of the Complaint.

12 205. Defendants are without knowledge or information sufficient to form a belief as to the  
13 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
14 Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this  
15 paragraph of the Complaint.

16 206. Defendants are without knowledge or information sufficient to form a belief as to the  
17 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
18 Celebrex® and, therefore, deny the same. Defendants deny any wrongful conduct and deny the  
19 remaining allegations in this paragraph of the Complaint.

20 207. Defendants deny any wrongful conduct and deny the remaining allegations in this  
21 paragraph of the Complaint.

22 208. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or  
23 damage, and deny the remaining allegations in this paragraph of the Complaint.

24 209. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or  
25 damage, and deny the remaining allegations in this paragraph of the Complaint.

26 210. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or  
27 damage, and deny the remaining allegations in this paragraph of the Complaint.

28 211. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or

1 damage, and deny the remaining allegations in this paragraph of the Complaint.

2 212. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or  
3 damage, and deny the remaining allegations in this paragraph of the Complaint.

4 **Response to Prayer for Relief**

5 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or  
6 damage, and deny the remaining allegations in paragraph of the Complaint headed “Prayer for  
7 Relief,” including all subparts.

8 **III.**

9 **GENERAL DENIAL**

10 Defendants deny all allegations and/or legal conclusions set forth in Plaintiff’s  
11 Complaint that have not been previously admitted, denied, or explained.

12 **IV.**

13 **AFFIRMATIVE DEFENSES**

14 Defendants reserve the right to rely upon any of the following or additional defenses to  
15 claims asserted by Plaintiff to the extent that such defenses are supported by information  
16 developed through discovery or evidence at trial. Defendants affirmatively show that:

17 **First Defense**

18 1. The Complaint fails to state a claim upon which relief can be granted.

19 **Second Defense**

20 2. Celebrex® is a prescription medical product. The federal government has preempted  
21 the field of law applicable to the labeling and warning of prescription medical products.  
22 Defendants’ labeling and warning of Celebrex® was at all times in compliance with applicable  
23 federal law. Plaintiff’s causes of action against Defendants, therefore, fail to state a claim upon  
24 which relief can be granted; such claims, if allowed, would conflict with applicable federal law  
25 and violate the Supremacy Clause of the United States Constitution.

26 **Third Defense**

27 3. At all relevant times, Defendants provided proper warnings, information, and  
28 instructions for the drug in accordance with generally recognized and prevailing standards in



1 existence at the time.

2 **Fourth Defense**

3 4. At all relevant times, Defendants' warnings and instructions with respect to the use of  
4 Celebrex® conformed to the generally recognized, reasonably available, and reliable state of  
5 knowledge at the time the drug was manufactured, marketed, and distributed.

6 **Fifth Defense**

7 5. Plaintiff's action is time-barred as it is filed outside of the time permitted by the  
8 applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

9 **Sixth Defense**

10 6. Plaintiff's action is barred by the statute of repose.

11 **Seventh Defense**

12 7. Plaintiff's claims against Defendants are barred to the extent Plaintiff was contributorily  
13 negligent, actively negligent or otherwise failed to mitigate their damages, and any recovery by  
14 Plaintiff should be diminished accordingly.

15 **Eighth Defense**

16 8. The proximate cause of the loss complained of by Plaintiff is not due to any acts or  
17 omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the  
18 part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not  
19 liable in any way.

20 **Ninth Defense**

21 9. The acts and/or omissions of unrelated third parties as alleged constituted independent,  
22 intervening causes for which Defendants cannot be liable.

23 **Tenth Defense**

24 10. Any injuries or expenses incurred by Plaintiff was not caused by Celebrex®, but were  
25 proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act  
26 of God.

27 **Eleventh Defense**

28 11. Defendants affirmatively deny that they violated any duty owed to Plaintiff.

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**Twelfth Defense**

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a “learned intermediary” in determining the use of the product. Celebrex® is a prescription medical product, available only on the order of a licensed physician. Celebrex® provided an adequate warning to Plaintiff’s treating and prescribing physicians.

**Thirteenth Defense**

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

**Fourteenth Defense**

14. Celebrex® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Celebrex® at the time of the occurrence of the injuries alleged by Plaintiff was legally adequate for its approved usages.

**Fifteenth Defense**

15. Plaintiff’s causes of action are barred in whole or in part by the lack of a defect as the Celebrex® allegedly ingested by Plaintiff was prepared in accordance with the applicable standard of care.

**Sixteenth Defense**

16. Plaintiff’s alleged injuries/damages, if any, were the result of misuse or abnormal use of the product Celebrex® after the product left the control of Defendants and any liability of Defendants is therefore barred.

**Seventeenth Defense**

17. Plaintiff’s alleged damages were not caused by any failure to warn on the part of Defendants.

**Eighteenth Defense**

18. Plaintiff’s alleged injuries/damages, if any, were the result of preexisting or subsequent

1 conditions unrelated to Celebrex®.

2 **Nineteenth Defense**

3 19. Plaintiff knew or should have known of any risk associated with Celebrex®; therefore,  
4 the doctrine of assumption of the risk bars or diminishes any recovery.

5 **Twentieth Defense**

6 20. Plaintiff is barred from recovering against Defendants because Plaintiff's claims are  
7 preempted in accordance with the Supremacy Clause of the United States Constitution and by  
8 the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

9 **Twenty-first Defense**

10 21. Plaintiff's claims are barred in whole or in part under the applicable state law because  
11 the subject pharmaceutical product at issue was subject to and received pre-market approval by  
12 the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

13 **Twenty-second Defense**

14 22. The manufacture, distribution, and sale of the pharmaceutical product referred to in  
15 Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes,  
16 and Plaintiff's causes of action are preempted.

17 **Twenty-third Defense**

18 23. Plaintiff's claims are barred in whole or in part by the deference given to the primary  
19 jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at  
20 issue under applicable federal laws, regulations, and rules.

21 **Twenty-fourth Defense**

22 24. Plaintiff's claims are barred in whole or in part because there is no private right of  
23 action concerning matters regulated by the Food and Drug Administration under applicable  
24 federal laws, regulations, and rules.

25 **Twenty-fifth Defense**

26 25. Plaintiff's claims are barred in whole or in part because Defendants provided adequate  
27 "direction or warnings" as to the use of the subject pharmaceutical product within the meaning  
28 of Comment j to Section 402A of the Restatement (Second) of Torts.

**Twenty-sixth Defense**

26. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Celebrex® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

**Twenty-seventh Defense**

27. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

**Twenty-eighth Defense**

28. Plaintiff's claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

**Twenty-ninth Defense**

29. To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead facts sufficient under the law to justify an award of punitive damages.

**Thirtieth Defense**

30. Defendants affirmatively aver that the imposition of punitive damages in this case would violate Defendants' rights to procedural due process under both the Fourteenth Amendment of the United States Constitution and the Constitutions of the States of Oklahoma and California, and would additionally violate Defendants' rights to substantive due process under the Fourteenth Amendment of the United States Constitution.

**Thirty-first Defense**

31. Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution.

**Thirty-second Defense**

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

**Thirty-third Defense**

33. Plaintiff's punitive damage claims are preempted by federal law.

**Thirty-fourth Defense**

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

**Thirty-fifth Defense**

35. Plaintiff failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

**Thirty-sixth Defense**

36. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

**Thirty-seventh Defense**

37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

**Thirty-eighth Defense**

38. To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution, and applicable provisions of the Constitutions of the States of Oklahoma and California. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages;

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(3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1, 111 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

#### **Thirty-ninth Defense**

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Celebrex®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

#### **Fortieth Defense**

40. The claims asserted in the Complaint are barred because Celebrex® was designed, tested, manufactured, and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

#### **Forty-first Defense**

41. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendants and over whom Defendants had no control and for whom Defendants may not be held accountable.

**Forty-second Defense**

42. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

**Forty-third Defense**

43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

**Forty-fourth Defense**

44. Plaintiff's claims are barred because Plaintiff's injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic, and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff, and were independent of or far removed from Defendants' conduct.

**Forty-fifth Defense**

45. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® did not proximately cause injuries or damages to Plaintiff.

**Forty-sixth Defense**

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff did not incur any ascertainable loss as a result of Defendants' conduct.

**Forty-seventh Defense**

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

**Forty-eighth Defense**

48. The claims must be dismissed because Plaintiff would have taken Celebrex® even if the product labeling contained the information that Plaintiff contends should have been provided.



**Forty-ninth Defense**

49. The claims asserted in the Complaint are barred because the utility of Celebrex® outweighed its risks.

**Fiftieth Defense**

50. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.

**Fifty-first Defense**

51. Defendants' liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiff.

**Fifty-second Defense**

52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

**Fifty-third Defense**

53. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiff's claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Celebrex®. Accordingly, Plaintiff's claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

**Fifty-fourth Defense**

54. Plaintiff's misrepresentation allegations are not stated with the degree of particularity

1 required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

2 **Fifty-fifth Defense**

3 55. Defendants state on information and belief that the Complaint and each purported cause  
4 of action contained therein is barred by the statutes of limitations contained in California Code  
5 of Civil Procedure §§ 335.1 and 338 and former § 340(3), and such other statutes of limitation  
6 as may apply.

7 **Fifty-sixth Defense**

8 56. Defendants state on information and belief that any injuries, losses, or damages suffered  
9 by Plaintiff was proximately caused, in whole or in part, by the negligence or other actionable  
10 conduct of persons or entities other than Defendants. Therefore, Plaintiff's recovery against  
11 Defendants, if any, should be reduced pursuant to California Civil Code § 1431.2.

12 **Fifty-seventh Defense**

13 57. To the extent that Plaintiff seeks punitive damages for an alleged act or omission of  
14 Defendants, no act or omission was oppressive, fraudulent, or malicious under California Civil  
15 Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive  
16 damages is also barred under California Civil Code § 3294(b).

17 **Fifty-eighth Defense**

18 58. Oklahoma's judicially-created definitions of manufacturing defect and design defect,  
19 and standard for determining whether there has been an actionable failure to warn, are  
20 unconstitutional in that, among other things, they are void for vagueness and an undue burden  
21 on interstate commerce, as well as an impermissible effort to regulate in an area that previously  
22 has been preempted by the federal government.

23 **Fifty-ninth Defense**

24 59. To the extent that Plaintiff seeks punitive damages for an alleged act or omission of  
25 Defendants, no act or omission was in reckless disregard for the rights of others, committed  
26 intentionally and with malice toward others in conduct life-threatening to humans, under Okla.  
27 Stat. tit. 23 § 9.1, and therefore, any award of punitive damages is barred. Any claim for  
28 punitive damages is also barred under Okla. Stat. tit. 23 § 9.1 and the Oklahoma State

1 Constitution.

2 **Sixtieth Defense**

3 60. Defendants reserve the right to supplement their assertion of defenses as they continue  
4 with their factual investigation of Plaintiff's claims.

5 **V.**

6 **PRAYER**

7 WHEREFORE, Defendants pray for judgment as follows:

- 8 1. That Plaintiff takes nothing from Defendants by reason of the Complaint;
- 9 2. That the Complaint be dismissed;
- 10 3. That Defendants be awarded their costs for this lawsuit;
- 11 4. That the trier of fact determine what percentage of the combined fault or other liability  
12 of all persons whose fault or other liability proximately caused Plaintiff's alleged  
13 injuries, losses, or damages is attributable to each person;
- 14 5. That any judgment for damages against Defendants in favor of Plaintiff be no greater  
15 than an amount which equals their proportionate share, if any, of the total fault or other  
16 liability which proximately caused Plaintiff's injuries and damages; and
- 17 6. That Defendants have such other and further relief as the Court deems appropriate.

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CORPORATION, and G.D. SEARLE  
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**JURY DEMAND**

Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC hereby demand a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

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